VI - 510 (K) SUMMARY

Submitted by:

Chelsea Mitchell
Ceremed, Inc.
3643 Lenawee Ave.
Los Angeles, California 90016
Tel: (310) 815-2125
Fax: (310) 815-2130

SEP 1 2 2013

Contact Person:	Chelsea Mitchell
Date Prepared	July 12, 2013
Common/Usual Name:	Soluble Synthetic Polymer Implant Material
Proprietary Name:	Adaptain™, Adaptain FastWrap ™, Envelock™, Biowai™
Regulation Number:	21 CFR 874.3620
Regulation Name:	Ear, nose and throat synthetic polymer material
Regulatory Class:	II
Product Code:	KHJ
Predicate Device:	Ceremed, Inc. Adaptain FastWrap ™, (K122561)

Description of the device:

Adaptain™ is a water-soluble, wax-like surgical implant material that will adhere to itself or hard surfaces with the application of firm pressure. Adaptain™ is designed to be utilized directly out of the package. The implant will soften as it is warmed. The surface of the implant becomes lubricious when wet, and the implant does not swell as it dissolves.

Adaptain™ is comprised of a sterile mixture of water-soluble alkylene oxide copolymers (AOC PolymerBlend™) and contains no other additives or colorants. Adaptain™ is supplied in a number of forms including bars, sticks, granules and sheets of various sizes with weights ranging from 0.5 to 5 grams each.

Adaptain™ is provided sterile by irradiation and must not be resterilized.

Intended use:
Adaptain™ is indicated for use as a water-soluble implant material and as a water-soluble space occupying material as an adjunct during the natural healing process.

Substantial equivalence:
The non-clinical evaluations used to determine substantial equivalence included indications, intended use, design, materials, sterilization, and performance. The comparison demonstrates that the device in this submission is identical in design, materials, indications, performance and sterilization to the predicate Adaptain FastWrap™ (K122561).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ceremed, Incorporated
Ms. Chelsea Mitchell
Vice President, Regulatory Affairs
3643 Lenawee Avenue
Los Angeles, California 90016

September 12, 2013

Re: K132198
Trade/Device Name: Adaptain ™, Adaptain FastWrap™, Envelock™, Biowai™
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose, and throat synthetic polymer material
Regulatory Class: Class II
Product Code: KHJ
Dated: July 12, 2013
Received: July 16, 2013

Dear Ms. Mitchell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. INDICATIONS FOR USE:

510 (k) Number (if known): K132198

Device Name: Adaptain™, Adaptain FastWrap ™, Envelock™, Biowai™

Indications For Use:
Adaptain™ is indicated for use as a water-soluble implant material and as a water-soluble space occupying material as an adjunct during the natural healing process.

Prescription Use_____X_____ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

CONCURRANCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K132198

Division Sign-Off

510(k) Number_____